21. (Amended) The lipidized antibody [A composition] of claim 20, wherein the antibody binds to an antigen intracellularly in living cells.

22. (Amended) The lipidized antibody of claim 21 [A composition of claim 22], wherein the antibody binds to the HIV-1 Tat protein intracellularly in HIV-infected human cells.

REMARKS

Claims 1-22 and 24 are pending in the above-referenced patent application. Claims 14-22 (note: 14-23 on the Office Action; claim 23 is no longer under consideration) are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-12, 24, and 29-33 of copending application Serial No. 08/483,944. Claims 1-5, 7-10, 12-22, and 24 are rejected under 35 U.S.C. § 112, first paragraph, as being allegedly non-enabled by the specification as filed. Claims 11-13, and 21-22 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite.

OBVIOUSNESS-TYPE DOUBLE-PATENTING REJECTION:

Claims 14-23 are provisionally rejected under the judicially created doctrine of obviousness-type double-patenting as being unpatentable over claims 1, 2, 4-12, 24, 29-33 of copending U.S. Patent Application Serial No. 08/483,944. The Examiner has indicated that this provisional rejection can be overcome by timely filing a Terminal Disclaimer.

Applicant acknowledges that copending U.S. Patent Application Serial No. 08/483,944 has claims that are similar to those in the present case. However, Applicant is entitled to at least one patent relating to the claimed invention and, thus, upon withdrawal of the other outstanding rejections/objections in the present case, Applicant will cancel the conflicting claims in copending U.S. Patent Application Serial No. 08/483,944 or, alternatively, he will file a Terminal Disclaimer. As such, Applicant respectfully requests that this provisional rejection be held in abeyance until the other outstanding objections/rejections have been withdrawn.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-5, 7-10, 12-22, and 24 are rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Specifically, the Examiner has stated that while the specification as filed is enabling for the use of glycyldioctadecylamide for lipidizing proteins in order to achieve intracellular localization of the lipidized protein, the specification allegedly does not enable the use of any other lipid having a hydrocarbon tail of greater than 12 carbons for making lipidized proteins that localize intracellularly. The Examiner further states that it is unpredictable whether lipidized proteins that contain an hydrocarbon tail of more than 12 carbons will localize intracellularly. Applicant respectfully traverses this rejection.

A particular claim is enabled by the disclosure in an application if the disclosure, at the time of filing, contains sufficient information so as to enable one of skill in the art to make and use the claimed invention without undue experimentation. *See, e.g., In re Wands*, 8 USPQ2d, 1400 (Fed. Cir. 1988), or MPEP § 2164.01. In addition, "the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." *See*, MPEP § 2164.01.

The present claims are directed to lipidized antibodies that localize intracellularly. Therefore, to make and use the invention, one of skill would have simply needed to obtain antibodies, obtain lipids, attach the lipids to the antibodies, and determine whether the resulting lipidized antibody is intracellular. Applicant points out that each of these requirements is amply taught in the specification as filed. For example, page 12, lines 18-37; page 13, lines 1-11; page 19, lines 34-37; page 20, lines 1-37; and page 21, line 1-12, *inter alia*, teach suitable antibodies and their preparation, and, for example, page 17, lines 20-37; page 18, lines 1-40; page 19, lines 1-2 teach suitable lipids for use with the methods of the present invention. In addition, page 15, lines 30-37; page 16, lines 1-32; page 33, lines 6-37; and page 34, lines 1-2, *inter alia*, teach how to attach a lipid to a protein. Furthermore, the present specification teaches a variety of methods for testing whether a lipidized protein

localizes intracellularly (*see*, for example, page 34, lines 17-36; page 35, lines 1-8; page 35, lines 13-37; and page 36, lines 1-23). Moreover, standard techniques were available at the time the application was filed for determining the cellular localization of a protein, *i.e.*, whether a protein is localized inside the cell or at the cell membrane. The specification thus discloses how to make lipidized proteins, and how to appropriately determine whether the lipidized protein localizes intracellularly. One of skill in the art would have, therefore, been able to make and practice the present invention.

The Examiner has focused on the selection of a precise lipid for lipidizing a protein alleging that one of skill would not have been able to know *a priori* whether using a particular lipid for lipidizing a protein would result in the intracellular localization of the lipidized protein. Applicant responds that the standard for enablement is not whether one can know beforehand which specific embodiments of an invention work, but rather whether undue experimentation is required to make and use the invention.

Furthermore, the first paragraph of U.S.C. § 112 does not require specific demonstration of particular embodiments of an invention. Indeed the courts have specifically held that, while a large number of examples are desirable, they are not required by the statute, even in complex technologies. *In re Strahilevitz* 212 USPQ 561 (CCPA 1982). The dispositive issue is not the number of examples provided or the specific demonstration of each particular embodiment of the invention, but whether one of skill could make and use the claimed invention based on the disclosure provided.

In the present case, Applicant has provided working examples demonstrating that the present methods can work under a number of conditions, and has provided assays with which any other lipid could be readily tested. For one of skill in the art, lipidizing a protein with any of the claimed lipids using the methods of the present invention, and testing whether the lipidized protein localizes intracellularly would have amounted to routine experimentation. In view of the above, Applicant respectfully submits that the claims of the present patent application are fully enabled by the specification.

Accordingly, Applicant urges the Examiner to withdraw this rejection under 35 U.S.C. § 112, first paragraph.

REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 11-13, 21, and 22 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, the Examiner has stated that claim 11 is allegedly indefinite because it is drawn to a method and yet is dependent on claim 14 which is a product claim. Claim 11 has been amended in order to correct the dependency. In view of this amendment, the Examiner's rejection is rendered moot.

The Examiner has further stated that claims 12 and 13 are allegedly indefinite because of improper dependency. Claim 12 has been amended in order to correct the dependency. Applicant points out that claim 13 is correctly dependent on claim 12. In view of this amendment, the Examiner's rejection is rendered moot.

The Examiner further rejects claims 21 and 22 as being allegedly indefinite in the recitation of the term "composition" which lacks an antecedent basis in claim 20. Claims 21 and 22 have been amended to delete the term "composition," and are now directed to a "lipidized antibody," consistent with claim 20. In view of this amendment, the Examiner's rejection is rendered moot.

Accordingly, Applicant urges the Examiner to withdraw this rejection under U.S.C. § 112, second paragraph.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

Kathleen L. Choi
Reg. No. 43,433

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
KLC:NS1

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